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DNH

Chronology of Events in Preparation of
ENVIRONMENTAL IMPACT STATEMENT:
GUIDELINES FOR RESEARCH INVOLVING
RECOMBINANT DNA MOLECULES

Dramatis Personae

DHEW/PHS

Charles Custard, Director, Office of Environmental Affairs
Paul Cromwell, Deputy Director, OEA
Boris Osheroff, Principal Environmental Officer/H
George H. Deming, Deputy Environmental Officer/H

NIH: OD Staff

Dr. Donald S. Fredrickson, Director, NIH
Dr. Ronald Lamont-Havers, Deputy Director (until 9/10/76)
Dr. DeWitt Stetten, Jr., Deputy Director for Science
Dr. Joseph G. Perpich, Associate Director for Program
Planning and Evaluation
Dr. Leon Jacobs, Associate Director for Collaborative Research
Dr. Philip Chen, Jr., Assistant Director for Intramural Affairs
Dr. Bernard Talbot, Special Assistant for Intramural Affairs

Other NIH Participants (alphabetical)

Michael Adler, Program Analyst, Division of Legislative Analysis
Dr. W. Emmett Barkley, Director of Research Safety, OD-NCI
W. T. Carrigan, Chief, Special Projects Branch, Office of
Legislative Analysis
Donald J. Dunsmore, Assistant to the Chief, Environmental Safety
Branch, Division of Research Services
Dr. William Gartland, Chief, Office of Recombinant DNA
Activities, National Institute of General Medical Sciences
Dr. Martin Gellert, Chief, Section on Metabolic Enzymology,
National Institute of Arthritis, Metabolism, & Digestive Diseases
Dr. Robert Martin, Chief, Section on Microbial Genetics,
National Institute of Arthritis, Metabolism, & Digestive Diseases
Vinson R. Oviatt, Chief, Environmental Safety Branch, Division
of Research Services
Dr. Wallace P. Rowe, Chief, Laboratory of Viral Diseases,
National Institute of Allergy and Infectious Diseases
Dr. Maxine F. Singer, Head, Nucleic Acid Enzymology Section,
Laboratory of Biochemistry, National Cancer Institute
Dr. Rudolf G. Wanner, Agency Environmental Officer

Advisors

Harold P. Green, legal consultant to NIH Director
Richard J. Riseberg, Legal Advisor, NIH (Office of the General
Counsel, DHEW)

Chronology

- 2/5/76 NIH work group (drawn from persons listed above) meets with NIH Director on NEPA requirements as applied to recombinant DNA research. (NIH experience with NEPA process dates from appointment of Environmental Officer in 1973; includes development of Environmental Impact Statement (EIS) for the NIH Master Plan on Construction, July 1976.)
- April 1976 NIH work groups discuss legal aspects of NEPA, ^{begin} conduct environmental impact assessment.
- 4/1-2/76 NIH Recombinant Advisory Committee (founded in October 1974) meets at NIH; informed of public commentators' request for an EIS on NIH-supported recombinant DNA research.
- 4/26/76 Analysis of issues in preparation for meeting with NIH Director.
- 4/30/76 NIH group meets with Director; decision to prepare NEPA document.
- May 1976 NIH work groups continue assessment.
- 5/7/76 Memo from Custard to Osheroff on applicability of NEPA to NIH actions such as recombinant DNA research.
- 5/14/76 NIH group meets with Director; decision to issue Environmental Impact Statement (EIS).
- 5/21/76 NIH meeting with DHEW (and PHS) officials--Custard, Cromwell, and Osheroff--concerning development of the NIH generic analysis, including an EIS on recombinant DNA.
- 5/27/76 Memo from Perpich to NIH Director on May 28 meeting on "NEPA and DNA Research."
- 5/28/76 NIH Director meets with staff to discuss progress on development of EIS. Analysis in process.
- 6/4/76 NIH staff meets; decision to produce a Working Draft (#1) by 6/18. Final Draft EIS to be published by 9/1/76.
- 6/10-11 Advisory Committee to Director (DAC) meets at NIH, discusses recombinant DNA, concurs in release of NIH Guidelines 6/23/76.

6/11/76 Working Draft #1 to Stetten.

6/14/76 Working Draft #1 circulated at NIH.

6/15/76 Singer assigned to write Working Draft #2.

6/22/76 NIH Director and staff meet with Warren Muir and Malcolm Bruce of the Council on Environmental Quality (CEQ). Custard and Cromwell present. Harold Green, consultant to NIH on NEPA, attends (and several subsequent meetings). Singer's outline of Draft #2 approved. Satisfaction with 9/1/76 release date.

6/23/76 Public release of NIH Guidelines. Preparation of EIS announced. Draft #2 circulated for comment to Custard, Cromwell, Osheroff, and NIH staff.

6/28/76 Green comments on Draft #2. Cromwell thanks Stetten for Draft #1.

6/30/76 NIH group meets with Osheroff et al. Working Draft #2 reviewed. Decision to rewrite according to original outline as presented to CEQ.

7/1/76 NIH work group meets to discuss Green's comments on Draft #2. Green suggests changing to format similar to Dunsmore/Singer first draft.

7/2/76 Memo from Wanner to Chen reviewing Working Draft #2.

7/6/76 Work group meets. Reviews comments on Draft #2, agrees to rewrite in DHEW/CEQ format.

7/7/76 Work group begins Working Draft #3. NIH Guidelines published in Federal Register.

7/13/76 Meeting of NIH staff with Stetten on status of Draft #3.

7/16/76 Work group assembles Draft #3.

7/19/76 Draft #3 distributed for review to 30 people, including Osheroff, Cromwell, and some non-Federal scientists.

7/28/76 Comments on Draft #3 sent to Chen, incorporating oral comments of Osheroff.

8/2/76 NIH staff meets, reports that Draft #3 review is under way, comments still arriving. Cromwell calls, promising comments on format.

- 8/5/76 Cromwell's comments on Draft #3 received; proposes certain changes.
- 8/12/76 NIH work group distributes Draft #4 to same group of 30.
- 8/16/76 NIH meeting with DHEW (and PHS)--Cromwell, Deming, NIH staff. Discuss Drafts #3 and #4. Lamont-Havers establishes 8/26/76 as date for issuance of Draft EIS (Draft #5) for public circulation.
- 8/19/76 DEIS cleared with NIH Director 8/19, Wanner 8/20. Memo from Cromwell to Osheroff, 8/19, says he is sending DEIS to CEQ.
- 8/23/76 Wanner receives call from Cromwell, who has received DEIS and requests distribution through Office of Environmental Affairs. Memo from OEA Director Custard to Osheroff advises due date for comments to be 10/18/76.
- 8/24/76 NIH orders 1,000 copies of Draft Environmental Impact Statement (DEIS) for distribution 9/1/76. (Distribution outlined in Perpich memo to Fredrickson, 8/26/76.)
- 8/26/76 Distribution planned. To include Asilomar Conference participants, Director's Advisory Committee members, private industry representatives with whom NIH Director met, all correspondents on recombinant DNA, health and safety officials at selected universities, local and State officials and organizations, Mayor of Cambridge and City Council members, and internal NIH. Cromwell to distribute to Federal agencies.
- 8/27/76 Distribution begun. (Thank-you notes date from 8/31 or earlier.)
- 8/31/76 Distribution to congressional staff--10 House, 18 Senate. (See Perpich memo.)
- 9/2/76 CEQ publishes notice in Federal Register; comments from the public requested by 10/18/76. HEW News gives notice to the media.
- 9/7/76 DEIS to Chairmen of Environmental Committees in House and Senate.
- 9/8/76 Notice of DEIS in NIH Record.
- 9/9/76 DEIS appears in Federal Register.
- 9/13/76 Notice of DEIS in NIH Guide for Grants and Contracts to 12,000 NIH awardees, requesting comments by 9/18/76.

9/22/76 Fredrickson testifies on recombinant DNA research at Senate hearings (Mary Miers' memo).

11/76 PHS representatives attend Biological Safety Conference at Fort Detrick. Dr. A.G. Wedum advises on safety questions. FDA and CDC consulted.

11/4/76 Meeting of Federal Interagency Committee on Recombinant DNA Research. Informed of progress on EIS.

11/16-12/7 Fredrickson meets with staff on comments.

12/29/76 Final EIS (FEIS) in progress. Draft prepared for review underlining proposed changes responsive to comments. [Director's Decision (Appendix J) bridges DEIS and FEIS and explains acceptance or rejection of all recommended changes.]

1/4/77 First draft of Final EIS distributed internally for review and comment.

1/18/77 NIH meeting with DHEW (and PHS)--Cromwell, Osheroff, Green attend. Cromwell recommends changes in format which Fredrickson agrees to attempt in next version, and Cromwell agrees to respond by 2/1/77. (See memo from Perpich to Fredrickson 1/19/77.)

1/21/77 Draft of Final EIS distributed.

2/2/77 Memo from Cromwell to Fredrickson. Ten-page critique of FEIS draft, advises thorough revision. NIH meeting with DHEW (and PHS)--Cromwell, Osheroff, Deming--regarding Cromwell's comments.

2/7/77 NIH meeting with DHEW (and PHS). Cromwell's recommended changes in format to be carried out in FEIS.

2/15/77 Fredrickson meets with NIH staff, approves FEIS, transmits it to Wanner.

2/16/77 FEIS carried to Osheroff.

2/18/77 Copies of FEIS carried (unofficially) from NIH to Cromwell.

2/22/77 Osheroff transmits FEIS to Custard.

2/25/77 Dixon memo to Secretary showing that H approved FEIS.